JUL 1 7 2000

K001296

510(k) Spinal Cord Immobilization and Traction System
Air Methods Corporation – Products Division

510(k) Summary

Proprietary Name:	Spinal Cord Immobilization and Traction System
Common Name:	Equipment, Powered, Traction
Classification:	II
Submitter's Details:	Air Methods Corporation – Products Division 7301 South Peoria Englewood, Colorado 80111 Phone: (303) 792-7427 Fax: (303) 792-7537 Mr. Paul Trese, Engineering Manager

Description:

The Spinal Cord Injury Transport System (SCITS) is a patient transport system designed to provide an increased level of patient care during aeromedical evacuation operations. The system mission is the evacuation of severely injured personnel, including spinal cord injury and burn victims from forward area care providers. The system can interface with a variety of aeromedical evacuation platforms as well as ground transport vehicles providing enhanced flexibility for transport. This pneumatic ambulatory traction device will provide pneumatic traction force to a patient's body in a manner that can be controlled and varied as needed. The SCITS can be used with accessories such as an IV pole and standard patient tray. This product is a combination of traction units and patient bed that are typically found to be separate units.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2000

Ms. Julie Chaffee, Sponsor
Cavendish Scott, Inc.
c/o Mr. Paul F. Trese
Air Methods Corporation
7301 South Peoria
Englewood, Colorado 80112

Re: K001296
Trade Name: Spinal Cord and Immobilization Traction System
Regulatory Class: II
Product Code: ITH and INT
Dated: April 21, 2000
Received: April 24, 2000

Dear Ms. Chaffee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K001296
Air Methods Corporation – Products Division

Device Name: Spinal Cord Immobilization and Traction system

Indications for Use:

The Spinal Cord Injury Transport System (SCITS) is a patient transport system designed to provide an increased level of patient care during aeromedical evacuation operations. The system mission is the evacuation of severely injured personnel, including spinal cord injury and burn victims from forward area care providers. The system can interface with a variety of aeromedical evacuation platforms as well as ground transport vehicles providing enhanced flexibility for transport. This pneumatic ambulatory traction device will provide pneumatic traction force to a patient's body in a manner that can be controlled and varied as needed. The SCITS can be used with accessories such as an IV pole and standard patient tray. This product is a combination of traction units and patient bed that are typically found to be separate units.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001296

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)